

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11435</b>	<b>Date: May 26, 2022</b>
	<b>Change Request 12761</b>

**SUBJECT: July 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to describe changes to and billing instructions for various payment policies implemented in the July 2022 OPPS update. The July 2022 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this CR. This Recurring Update Notification applies to Chapter 4, section 50.8 (Annual Updates to the OPPS Pricer for Calendar Year (CY) 2007 and Later).

The July 2022 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2022 I/OCE CR.

**EFFECTIVE DATE: July 1, 2022**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: July 5, 2022**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	4/10.2.3/Comprehensive APCs

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 11435	Date: May 26, 2022	Change Request: 12761
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**EFFECTIVE DATE: July 1, 2022**

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**IMPLEMENTATION DATE: July 5, 2022**

## **I. GENERAL INFORMATION**

**A. Background:** This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the July 2022 OPPS update. The July 2022 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.8 (Annual Updates to the OPPS Pricer for Calendar Year (CY) 2007 and Later).

The July 2022 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2022 I/OCE CR.

## **B. Policy:**

### **1. Covid-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update**

Since February 2020, CMS has recognized several Covid-19 laboratory tests and related services. The codes are listed in Table 1, attachment A, along with their OPPS status indicators. The codes, along with their short descriptors and status indicators are also listed in the July 2022 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2022 OPPS/Ambulatory Surgical Center (ASC) final rule.

### **2. Over-the-Counter (OTC) COVID-19 Tests Demonstration**

In response to the COVID-19 Public Health Emergency (PHE), under the authority of Section 402(a)(1)(B) of the Social Security Amendments of 1967, the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Payment for Over-the-Counter (OTC) COVID-19 Tests Demonstration (“the demonstration”) to cover and pay for OTC COVID-19 tests for eligible Medicare beneficiaries.

CMS established the Level II HCPCS code K1034 that will be payable for all eligible providers under the demonstration. This HCPCS code represents a quantity of one single test and is inclusive of all types of FDA approved, authorized or cleared COVID-19 tests that are intended for self-administration and where the specimen is self-collected. HCPCS code K1034 will be effective on the date of announcement of the demonstration, 04/04/2022, and will remain effective for dates of service through the end of the COVID-19 PHE.

The code is listed in Table 2, attachment A, along with its OPPS status indicator. The code, along with its short descriptor and status indicator, is also listed in the July 2022 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2022 OPPS/Ambulatory Surgical Center (ASC) final rule.

### **3. New Covid-19 CPT Vaccines and Administration Codes**

American Medical Association (AMA) has been issuing unique Current Procedural Terminology (CPT) Category I codes which are developed based on collaboration with Centers for Medicare and Medicaid

Services (CMS) and Centers for Disease Control and Prevention (CDC) for each coronavirus vaccine as well as administration codes unique to each such vaccine and dose. These codes are effective upon receiving Emergency Use Authorization (EUA) or approval from the Food and Drug Administration (FDA).

On March 7, 2022, the AMA released two new CPT Category I codes. A new code describing an additional presentation of the Moderna COVID-19 vaccine for booster vaccination doses (91309) and an affiliated code that describes the service to administer the booster dose (0094A).

The Centers for Medicare & Medicaid Services (CMS) identifies an effective date of 03/29/2022 for the Moderna COVID-19 vaccine administration CPT code 0094A, which describes the service to administer the booster dose. This effective date corresponds with updates to Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs) and/or approvals. The Moderna COVID-19 vaccine product CPT code 91309 will be effective 03/29/2022. CMS will provide future direction to the contractors as EUAs and/or approvals become available.

Effective March 29, 2022, CPT code 0094A is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment) and APC 9398 (Covid-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) in the July 2022 I/OCE update.

Effective March 29, 2022, CPT code 91309 is assigned to status indicator “L” (Not paid under OPSS. Paid at reasonable cost; not subject to deductible or coinsurance) in the July 2022 I/OCE update.

Beneficiary cost sharing shall not be applied to the new vaccine and administration code.

On April 26, 2022, the AMA released three new CPT Category I codes. Sanofi Pasteur booster vaccine for adults 18 year of age and older (91310) and its associated administration code (0104A) as well as Pfizer booster code (0074A) for patients 5-11 years old. These codes will be available for use once they receive EUA or approval from the FDA.

Table 3, attachment A, lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the July 2022 OPSS Addendum B that is posted on the CMS website. For information on the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2022 OPSS/ASC final rule for the latest definitions.

#### **4. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective July 1, 2022**

The AMA CPT Editorial Panel established 9 new PLA codes, specifically, CPT codes 0323U through 0331U, effective July 1, 2022.

Table 4, attachment A, lists the long descriptors and status indicators for the codes. The codes have been added to the July 2022 I/OCE with an effective date of July 1, 2022. In addition, the codes, along with their short descriptor and status indicators, are listed in the July 2022 OPSS Addendum B that is posted on the CMS website. For more information on OPSS status indicators, refer to OPSS Addendum D1 of the Calendar Year 2022 OPSS/ASC final rule for the latest definitions.

#### **5. Advanced Diagnostic Laboratory Tests (ADLT) Under the Clinical Lab Fee Schedule (CLFS)**

On March 24, 2022, CMS announced the approval of one laboratory test as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. We note that, under the OPSS, tests that receive ADLT status under section 1834A(d)(5)(A) of the Act are assigned to status indicator “A”. The laboratory test is listed in Table 5, attachment A.

Based on the ADLT designation, we revised the OPSS status indicator for HCPCS codes 0108U to “A” (Not paid under OPSS. Paid by MACs under a fee schedule or payment system other than OPSS) effective July 1, 2022. However, because the ADLT designation was made in March 2022, it was too late to include this

change in the April 2022 I/OCE Release and the April 2022 OPPS update; therefore, we are including this change in the July 2022 I/OCE Release with an effective date of March 24, 2022.

For the latest list of ALDT approved tests under the CLFS, refer to this CMS website:

<https://www.cms.gov/files/document/advanced-diagnostic-laboratory-tests-under-medicare-clfs.pdf>. For more information on the OPPS status indicator “A”, refer to OPPS Addendum D1 of the CY 2022 OPPS/ASC final rule for the latest definitions.

## **6. New CPT Category III Codes Effective July 1, 2022**

The American Medical Association (AMA) releases CPT Category III codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January.

For the July 2022 update, CMS is implementing 24 new CPT Category III codes that the AMA released in January 2022 for implementation on July 1, 2022. The status indicators and APC assignments for these codes are shown in Table 6, attachment A. CPT codes 0714T through 0737T have been added to the July 2022 I/OCE with an effective date of July 1, 2022. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the July 2022 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2022 OPPS/ASC final rule for the latest definitions.

## **7. Procedures Assigned to New Technology APCs**

### **a. The Optellum Lung Cancer Prediction (LCP) Procedure**

AMA is establishing a new CPT code, 0721T, to describe the Optellum LCP service, which applies an algorithm to a patient’s CT scan to produce a raw risk score for a patient’s pulmonary nodule. The risk score is used by the physician to quantify the risk of lung cancer and to help determine whether or not to refer the patient to a pulmonologist. This service is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1508 (New Technology - Level 8 (\$600 - \$700)) effective July 1, 2022.

### **b. The Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) Procedure**

AMA is establishing a new CPT code, 0723T, to describe the Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) service. The QMRCP performs a quantitative assessment of the biliary tree and gallbladder that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. This service is assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple, separate APC assignment), APC 1511 (New Technology - Level 11 (\$900 - \$1,000)) effective July 1, 2022.

Table 7, attachment A, lists the official long descriptors, status indicators, and APC assignments for CPT codes 0721T and 0723T. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2022 OPPS/ASC final rule for the latest definitions. These codes, along with their short descriptors, status indicators, and payment rates, are also listed in the July 2022 Update of the OPPS Addendum B.

### **c. Retinal Prosthesis Implant Procedure – Status indicators and APC Assignments for the Argus® II Device, the Argus® II Implantation Procedure, and the Argus® II Programming Procedures**

We have determined that the Argus® II device, which is the device that is implanted for the retinal prosthesis implant procedure, is no longer available in the marketplace. We also understand that outpatient hospital providers are no longer performing the Argus® II implantation procedure, and we understand that providers are no longer providing programming services for the Argus® II. Therefore, we are changing the status indicators and APC assignments for CPT codes 0100T, 0472T, 0473T, and C1841 as shown in Table

8, Attachment A effective July 1, 2022.

#### **d. CardiAMP Cell Therapy IDE Descriptor Change and APC Reassignment Retroactive to April 1, 2022**

HCPCS code C9782 (CardiAMP cell therapy IDE study) was established April 1, 2022 and assigned to APC 1574 with a status indicator “T.” We have revised the descriptor for HCPCS code C9782 to specify the inclusion of the device. Additionally, we determined that APC 1590 most accurately accounts for the resources associated with furnishing CardiAMP cell therapy IDE. The revised descriptor and APC assignment are shown in Table 9.

#### **8. Comprehensive APC (C-APC) Exclusion List Changes**

We are revising Pub. 100-04, the Claims Processing Manual, Chapter 4, section 10.2.3 to add over-the-counter (OTC) COVID-19 tests to the C-APC exclusion list.

#### **9. Drugs, Biologicals, and Radiopharmaceuticals**

##### **a. New CY 2022 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Starting July 1, 2022**

Nine new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available starting on July 1, 2022. These drugs and biologicals will receive drug pass-through status starting July 1, 2022. These HCPCS codes are listed in Table 10, attachment A.

##### **b. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2022**

Sixteen new drug, biological, and radiopharmaceutical HCPCS codes will be established on July 1, 2022. These HCPCS codes are listed in Table 11, attachment A.

##### **c. HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Will Retroactively Change from Non-Payable Status to Payable Status Effective April 1, 2022**

The status indicator for HCPCS code J0879 (Injection, difelikefalin, 0.1 microgram, (for End Stage Renal Disease on dialysis)) effective April 1, 2022, will be changed retroactively from status indicator “E2” to status indicator “K” in the July 2022 Update. This code is reported in Table 12, attachment A.

##### **d. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)**

For CY 2022, payment for the majority of nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP + 6 percent of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP – 22.5 percent (or ASP - 22.5 percent of the biosimilar’s ASP if a biosimilar is acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical. In CY 2022, a single payment of ASP + 6 percent for pass-through drugs, biologicals, and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective July 1, 2022, payment rates for many drugs and biologicals have changed from the values published in the CY 2022 OPPTS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the fourth quarter of CY 2021. In cases where adjustments to payment rates are necessary,

changes to the payment rates will be incorporated in the July 2022 Fiscal Intermediary Standard System (FISS) release. CMS is not publishing the updated payment rates in this Change Request implementing the July 2022 update of the OPPTS. However, the updated payment rates effective July 1, 2022, can be found in the July 2022 update of the OPPTS Addendum A and Addendum B on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS>

#### **e. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates**

Some drugs and biologicals paid based on ASP methodology will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS website on the first date of the quarter at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPTS-Restated-Payment-Rates.html>

Providers may resubmit claims that were affected by adjustments to a previous quarter's payment files.

### **10. Skin Substitutes**

The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. For payment packaging purposes, the skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has pricing data that demonstrates that the cost of the product is above either the mean unit cost of \$48 or the per day cost of \$949 for CY 2022.

#### **a. New Skin Substitute Products as of July 1, 2022**

There are three new skin substitute HCPCS codes that will be active as of July 1, 2022. These codes are listed in Table 13, attachment A.

#### **b. Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of July 1, 2022**

There are four skin substitute HCPCS codes that will be reassigned from the low cost skin substitute group to the high cost skin substitute group as of July 1, 2022. The codes are listed in Table 14, attachment A.

#### **c. Skin Substitute Product Defined as a Powdered Skin Substitute Retroactive to January 1, 2022**

The descriptor of HCPCS code A2004 has been revised retroactive to January 1, 2022, as shown in Table 15, attachment A. Since HCPCS code A2004 is no longer described as a graft skin substitute product for the period of January 1, 2022, through June 30, 2022, the code is not assigned to either the low cost skin substitute group or the high cost skin substitute group retroactive to January 1, 2022, as shown in Table 16, attachment A.

#### **d. Skin Substitute Product Reassigned to the High Cost Skin Substitute Group retroactively to April 1, 2022**

The manufacturer of skin substitute product HCPCS code A2001 (Innovamatrix ac, per square centimeter) submitted a request before the development of the April 2022 OPPTS Quarterly Update to have HCPCS code A2001 assigned to the high cost skin substitute group. Because of an error, the request was not considered for the April 2022 OPPTS Quarterly Update even though we determined that skin substitute products assigned to the HCPCS code range A2001 – A2013 could be payable in the OPPTS starting April 1, 2022. Therefore, we are retroactively assigning HCPCS code A2001 to the high cost skin substitute group effective April 1, 2022 as shown in Table 17.

## 11. Coverage Determinations

As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPPTS does not imply coverage by the Medicare program but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

## II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			D M E  M A C	Shared- System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
12761.1	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of the July 2022 OPPTS I/OCE.	X		X						
12761.2	Medicare contractors shall remove any editing that manually applied Reason Code W7013 to Type of Bill (TOB) 012x, and 013x claim lines with HCPCS J0879 from the April 2022 quarterly release CR and reprocess any claims where the Reason Code W7013 was manually applied in error.	X		X						

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
12761.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X		X		

#### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:
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**Section B: All other recommendations and supporting information:** N/A

#### V. CONTACTS

**Pre-Implementation Contact(s):** Marina Kushnirova, marina.kushnirova@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

#### VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 1**

## Attachment A – Tables for the Policy Section

**Table 1. – Covid-19 Laboratory Tests and Service and Other Laboratory Tests Codes**

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>Add Date</b>	<b>OPPS SI</b>	<b>OPPS APC</b>
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	02/04/2020	A	N/A
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	02/04/2020	A	N/A
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source	03/01/2020	Q1	5731
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source	03/01/2020	B	N/A
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source	03/01/2020	B	N/A
86328	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020	A	N/A
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	08/10/2020	A	N/A
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	08/10/2020	A	N/A
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative	09/08/2020	A	N/A
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020	A	N/A
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])	06/25/2020	A	N/A
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	03/13/2020	A	N/A
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)	02/21/2022	A	N/A

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>Add Date</b>	<b>OPPS SI</b>	<b>OPPS APC</b>
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A	N/A
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A	N/A
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	05/20/2020	A	N/A
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	06/25/2020	A	N/A
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	06/25/2020	A	N/A
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	08/10/2020	A	N/A
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum	08/10/2020	A	N/A
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [ha], procollagen iii amino terminal peptide [piin], tissue inhibitor of metalloproteinase 1 [timp-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years	04/01/2020	Q4	N/A

**Table 2. — Over-the-Counter (OTC) COVID-19 Tests Demonstration**

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>Add Date</b>	<b>OPPS SI</b>	<b>OPPS APC</b>
K1034	Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count	04/04/2022	A	N/A

**Table 3. — Covid-19 Vaccine Product and Administration CPT Codes**

<b>CPT Code</b>	<b>Type</b>	<b>Labeler</b>	<b>Long Descriptor</b>
91300	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use
0001A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose
0002A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose
0003A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; third dose
0004A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; booster dose
91301	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use
0011A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease

			[COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose
0012A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose
0013A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; third dose
91302	Vaccine/ Product Code	AstraZeneca/ University of Oxford	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 <sup>10</sup> viral particles/0.5mL dosage, for intramuscular use
0021A	Administration/ Immunization Code	AstraZeneca/ University of Oxford	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 <sup>10</sup> viral particles/0.5mL dosage; first dose
0022A	Administration/ Immunization Code	AstraZeneca/ University of Oxford	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 <sup>10</sup> viral particles/0.5mL dosage; second dose
91303	Vaccine/ Product Code	Janssen/Johnson&Johnson	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free,

			5x10 <sup>10</sup> viral particles/0.5mL dosage, for intramuscular use
0031A	Administration/ Immunization Code	Janssen/Johnson&Johnson	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10 <sup>10</sup> viral particles/0.5mL dosage; single dose
0034A	Administration/ Immunization Code	Janssen/Johnson&Johnson	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x10 <sup>10</sup> viral particles/0.5mL dosage; booster dose
91304	Vaccine/ Product Code	Novavax	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use
0041A	Administration/ Immunization Code	Novavax	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; first dose
0042A	Administration/ Immunization Code	Novavax	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; second dose

91305	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, trissucrose formulation, for intramuscular use
0051A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; first dose
0052A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; second dose
0053A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; third dose
0054A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; booster dose
91306	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein,

			preservative free, 50 mcg/0.25 mL dosage, for intramuscular use
0064A	Administration/ Immunization Code	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, booster dose
91307	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
0071A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose
0072A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose
0073A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose

0074A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; booster dose
91308	Vaccine/ Product Code	Pfizer-BioNTech	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
0081A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose
0082A	Administration/ Immunization Code	Pfizer-BioNTech	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose
91309	Vaccine/ Product Code	Moderna	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use
0094A	Administration/	Moderna	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2

	Immunization Code		(SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, booster dose
91310	Vaccine/ Product Code	Sanofi Pasteur	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, for intramuscular use
0104A	Administration/ Immunization Code	Sanofi Pasteur	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, booster dose

**Table 4. — PLA Coding Changes Effective July 1, 2022**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>OPPS SI</b>
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi	Q4
0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug	A
0325U	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug	A
0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A

0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed	A
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service	Q4
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations	A
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	Q4
0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations	A

**Table 5. – Advanced Diagnostic Laboratory Tests (ADLT) Under the Clinical Lab Fee Schedule (CLFS)**

Lab Name	Test Name	CPT Code	CPT Long Descriptor
Cernostics/Castle	TissueCypherBarrett's Esophagus Assay	0108U	Gastroenterology (Barrett's esophagus), whole slide– digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer

**Table 6. — CPT Category III Codes Effective July 1, 2021**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>OPPS SI</b>	<b>OPPS APC</b>
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance	J1	5375
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	N	N/A
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score	Q1	5733
0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs	E1	N/A
0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral	E1	N/A
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment	E1	N/A
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	S	5722
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	N	N/A

0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	N	N/A
0725T	Vestibular device implantation, unilateral	E1	N/A
0726T	Removal of implanted vestibular device, unilateral	E1	N/A
0727T	Removal and replacement of implanted vestibular device, unilateral	E1	N/A
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming	E1	N/A
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming	E1	N/A
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance	E1	N/A
0731T	Augmentative AI-based facial phenotype analysis with report	S	5733
0732T	Immunotherapy administration with electroporation, intramuscular	E1	N/A
0733T	Remote body and limb kinematic measurement-based real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days	Q1	5741
0734T	Remote body and limb kinematic measurement-based therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month	B	N/A
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	N	N/A
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter	Q1	5733

0737T	Xenograft implantation into the articular surface	E1	N/A
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**Table 7. — New CPT Codes Assigned to New Technology APCs Effective July 1, 2022**

CPT Code	Long Descriptor	SI	APC	APC Title
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508	New Technology - Level 8 (\$600-\$700)
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511	New Technology - Level 11 (\$900-\$1,000)

**Table 8 - Status Indicator and APC Assignments for the Argus® II Device, the Argus® II Implantation Procedure, and the Argus® II Programming Procedures Effective July 1, 2022**

CPT Code	Long Descriptor	April 2022 OPPS SI	April 2022 OPPS APC	July 2022 OPPS SI	July 2022 OPPS APC
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	E2	N/A
0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional	Q1	5743	E2	N/A
0473T	Device evaluation and interrogation of intraocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional	Q1	5742	E2	N/A

C1841	Retinal prosthesis, includes all internal and external components	N	N/A	E2	N/A
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**Table 9 - Status Indicator and APC Assignment for the CardiAMP Cell Therapy IDE**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>SI</b>	<b>APC</b>	<b>APC Title</b>
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590	New Technology - Level 39 (\$15,001-\$20,000)

**Table 10. — New CY 2022 HCPCS Codes Effective July 1, 2022 for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status**

<b>CY 2022 HCPCS Code</b>	<b>CY 2022 Long Descriptor</b>	<b>CY 2022 SI</b>	<b>CY 2022 APC</b>
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443
C9094	Inj, sutimlimab-jome, 10 mg	G	9444
C9095	Inj, tebentafusp-tebn, 1 mcg	G	9446
C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447
C9097	Inj, faricimab-svoa, 0.1 mg	G	9496
C9098	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498
J1306	Injection, inclisiran, 1 mg	G	9004
J2356	Injection, tezepelumab-ekko, 1 mg	G	9008

<b>CY 2022 HCPCS Code</b>	<b>CY 2022 Long Descriptor</b>	<b>CY 2022 SI</b>	<b>CY 2022 APC</b>
J9332	Injection, efgartigimod alfa-fcab, 2mg	G	9010

**Table 11. — Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2022**

<b>New HCPCS Code</b>	<b>Old HCPCS Code</b>	<b>Long Descriptor</b>	<b>SI</b>	<b>APC</b>
A9596	NA	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443
A9601	NA	Flortaucipir f 18 injection, diagnostic, 1 millicurie	E2	NA
C9094	NA	Inj, sutimlimab-jome, 10 mg	G	9444
C9095	NA	Inj, tebentafusp-tebn, 1 mcg	G	9446
C9096	NA	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447
C9097	NA	Inj, faricimab-svoa, 0.1 mg	G	9496
C9098	NA	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498
J0739	NA	Injection, cabotegravir, 1 mg	E1	N/A
J1306	NA	Injection, inclisiran, 1 mg	G	9004
J1551	NA	Injection, immune globulin (cutaquig), 100 mg	K	9007
J2356	NA	Injection, tezepelumab-ekko, 1 mg	G	9008
J2779	C9093	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg	G	9439
J2998	C9090	Injection, plasminogen, human-tvmh, 1 mg	G	9206
J3299	C9092	Injection, triamcinolone acetone (xipere), 1 mg	G	9358
J9331	C9091	Injection, sirolimus protein-bound particles, 1 mg	G	9241
J9332	NA	Injection, efgartigimod alfa-fcab, 2mg	G	9010

**Table 12. — HCPCS Code for Drugs, Biologicals, and Radiopharmaceuticals that Will Retroactively Change from Non-Payable Status to Payable Status Effective April 1, 2022**

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>Old SI</b>	<b>New SI</b>	<b>New APC</b>	<b>Effective Date</b>
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	E2	K	9202	04/01/2022

**Table 13. — New Skin Substitute Products Low Cost Group/High Cost Group Assignment Effective July 1, 2022**

<b>CY 2022 HCPCS Code</b>	<b>Short Descriptor</b>	<b>CY 2022 SI</b>	<b>Low/High Cost Skin Substitute</b>
Q4259	Celera per sq cm	N	Low

Q4260	Signature apatch, per sq cm	N	Low
Q4261	Tag, per square centimeter	N	Low

**Table 14. — Skin Substitute Products Reassigned to the High Cost Skin Substitute Group as of July 1, 2022**

<b>CY 2022 HCPCS Code</b>	<b>CY 2022 Short Descriptor</b>	<b>CY 2022 SI</b>	<b>Old Low/High Cost Skin Substitute Group</b>	<b>July 2022 Low/High Cost Skin Substitute Group</b>
A2001	Innovamatrix ac, per sq cm	N	Low	High
A2002	Mirragen adv wnd mat per sq	N	Low	High
Q4229	Cogenex amnio memb per sq cm	N	Low	High
Q4258	Enverse, per sq cm	N	Low	High

**Table 15. — Skin Substitute Product Defined as a Powdered Skin Substitute Retroactive to January 1, 2022**

<b>HCPCS Code</b>	<b>Old Short Descriptor</b>	<b>New Short Descriptor (Retroactive to January 1, 2022)</b>
A2004	Xcellistem, per sq cm	Xcellistem, 1 mg

**Table 16. — Skin Substitute Product Removed from the Low Cost Skin Substitute Group Retroactive to January 1, 2022**

<b>HCPCS Code</b>	<b>New Short Descriptor (Retroactive to January 1, 2022)</b>	<b>CY 2022 SI</b>	<b>Old Low/High Cost Skin Substitute Group Assignment</b>	<b>New Low/High Cost Skin Substitute Group Assignment (Retroactive to January 1, 2022)</b>
A2004	Xcellistem, 1 mg	N	Low	None

**Table 17. — Skin Substitute Product Reassigned to the High Cost Skin Substitute Group retroactively to April 1, 2022**

<b>CY 2022 HCPCS Code</b>	<b>CY 2022 Short Descriptor</b>	<b>CY 2022 SI</b>	<b>Old Low/High Cost Skin Substitute Group April 1 – June 30, 2022</b>	<b>New Low/High Cost Skin Substitute Group April 1 – June 30, 2022</b>
A2001	Innovamatrix ac, per sq cm	N	Low	High

### 10.2.3 - Comprehensive APCs

*(Rev.11435; Issued:05-26-22; Effective:07-01-22; Implementation:07-05-22)*

Comprehensive APCs provide a single payment for a primary service, and payment for all adjunctive services reported on the same claim is packaged into payment for the primary service. With few exceptions, all other services reported on a hospital outpatient claim in combination with the primary service are considered to be related to the delivery of the primary service and packaged into the single payment for the primary service.

HCPCS codes assigned to comprehensive APCs are designated with status indicator J1, See Addendum B at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS> for the list of HCPCS codes designated with status indicator J1.

Claims reporting at least one J1 procedure code will package the following items and services that are not typically packaged under the OPPTS:

- major OPPTS procedure codes (status indicators P, S, T, V)
- lower ranked comprehensive procedure codes (status indicator J1)
- non-pass-through drugs and biologicals (status indicator K)
- blood products (status indicator R)
- DME (status indicator Y)
- therapy services (HCPCS codes with status indicator A reported on therapy revenue centers)

The following services are excluded from comprehensive APC packaging:

- ambulance services
- brachytherapy sources (status indicator U)
- diagnostic and mammography screenings
- physical therapy, speech-language pathology and occupational therapy services reported on a separate facility claim for recurring services
- pass-through drugs, biologicals, and devices (status indicators G or H)
- preventive services defined in 42 CFR410.2
- self-administered drugs (SADs) - drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service
- services assigned to OPPTS status indicator F (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition)
- services assigned to OPPTS status indicator L (influenza and pneumococcal pneumonia vaccines)
- certain Part B inpatient services – Ancillary Part B inpatient services payable under Part B when the primary J1 service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only)
- services assigned to a New Technology APC.
- For the remainder of the PHE for COVID-19,
  - *Over-the-counter (OTC) COVID-19 tests*
  - New COVID-19 treatments that meet the following criteria:
    - 1) The treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section “I. Criteria for Issuance of Authorization” of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19
    - 2) The emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

The single payment for a comprehensive claim is based on the rate associated with either the J1 service or the specific combination of J2 services. When multiple J1 services are reported on the same claim, the single payment is based on the rate associated with the highest ranking J1 service. When certain pairs of J1 services (or in certain cases a J1 service and an add-on code) are reported on the same claim, the claim is eligible for a complexity adjustment, which provides a single payment for the claim based on the rate of the next higher comprehensive APC within the same clinical family. When a J1 service and a J2 service are reported on the same claim, the single payment is based on the rate associated with the J1 service, and the combination of the J1 and J2 services on the claim does not make the claim eligible for a complexity adjustment. Note that complexity adjustments will not be applied to discontinued services (reported with mod -73 or -74).